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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,241	08/05/2003	Zhen Zhang	58369 (71699)	6657

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EXAMINER

LEBEDEVA, MARINA I

ART UNIT PAPER NUMBER

1631

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/635,241

Applicant(s)

ZHANG ET AL.

Examiner

Marina Lebedeva

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-111 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-111 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: a set of learning algorithms as recited in claims 3, 4, 38, 39, 79, and 80.

Specie B: a set of training analysis as recited in claims 5-7, 40-43, and 81-84.

Specie C: a biological state class as recited in claims 10-16, 46-52, and 87-93.

Specie D: a candidate biomarker as recited in claims 17, 53, and 94.

Specie E: a component as recited in claims 19, 55, and 96.

Specie F: an expression profile assay as recited in claims 21-26, 57-62, and 98-103.

Specie G: a binding partner as recited in claims 29, 65, and 106.

Specie H: an assay to measure level of data elements as recited in claims 32-33, 67-68, and 108-109.

Species of group A, learning algorithms are divergent because profiles represented by the data sets are different and independent from each other. Data generated by one type of algorithm is expected to be different from data generated by any other type of algorithms.

Species of group B, a vector machine analysis, a linear discriminating analysis, and a unified maximum separation analysis algorithms are divergent because they are separate arts and data for each analysis are independent from each other.

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Species of group C, biological states are patentably distinct because they are structurally unrelated, each has a distinct structure and function, therefore data for each state are independent.

Species of group D, biomarkers such as a diagnostic, a risk of developing, a risk of recurrence, and stage of disease are divergent because they are structurally and functionally different, and data generated from one type of profile is different from data generated by any other type of profile.

Species of group E, nucleic acids, proteins, polypeptides, peptides, carbohydrates are unrelated because they have different chemical structure and function, therefore data for each component are independent.

Species of group F, expression profile assays are patentably distinct because they are structurally unrelated, and each has a distinct chemical composition and function, therefore data for each profile are independent.

Species of group G, binding partners are separate arts, they are structurally and functionally distinct and data for each combination are independent from each other.

Species of group H, SELDI and immunoassay are divergent because they are separate arts and data for each analysis are independent from each other.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 2, 8, 9, 18, 20, 27-28, 30-31, 34-37, 44, 45, 54, 56, 63-64, 66, 69-78, 85-86, 95, 97, 104-105, 107, 110-111 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lebedeva whose telephone number is (571)272-6101. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lebedeva  
Examiner  
Art Unit 1631

ml

MARJORIE MORAN  
PATENT EXAMINER

*Marjorie A. Moran*  
12/15/04